



CAU 1646 \$

PATENT  
Attorney Docket No. HUV-032.01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Carmen V. Pepicelli *et al.*

Serial No.: 09/394,020

Filing Date: September 10, 1999

For: *Regulation of Lung Tissue by Hedgehog-like  
Polypeptides, and Formulations and Uses Related  
Thereto*

Art Unit: 1646

Examiner: J. Andres

TECH CENTER 1600/2900

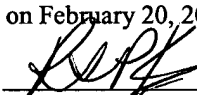
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**CERTIFICATE OF MAILING**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231 on February 20, 2001.

  
Robert king

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

**RESPONSE TO RESTRICTION REQUIREMENT/SPECIES ELECTION**

In response to the Restriction Requirement/Species Election dated December 18, 2000, Applicants provisionally elect with traverse the invention set forth in Group I, claims 1-17, and species g corresponding to SEQ ID NO: 15. Applicants have elected a sonic hedgehog (shh) species (SEQ ID NO: 15) which correlates to the consensus sequence of claim 11 (SEQ ID NO: 21).

In the restriction requirement under 35 U.S.C. § 121, the Examiner alleges that there are three distinct inventions as follows:

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- (I) Claims 1-17, drawn to a methods of using a hedgehog therapeutics, classified in class 514, subclass 2.
- (II) Claims 1-4 and 18-21, drawn to methods of using ptc therapeutics, classified in class 514, subclass 2.
- (III) Claims 1-4, drawn to methods of using FGF-10, classified in class 514, subclass 2.”

According to the Examiner, “These inventions are drawn to methods of use of entirely different proteins, having different structures, different functions, and a different status in the art. Claims 1-4 are listed in all groups because they are drawn to methods using each of these different proteins. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.”

Applicants respectfully traverse this restriction. The Examiner’s attention is directed to M.P.E.P. § 803, which states that: “If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions.” Thus, for a restriction requirement to be valid, the Examiner must establish the following two criteria:

- (1) the existence of independent and distinct inventions (35 U.S.C. § 121); and
- (2) that the search and examination of the entire application cannot be made without serious burden (M.P.E.P. § 803).

Applicants respectfully submit that the Examiner has not shown that the second requirement has been met with respect to the Groups above. In particular, Applicants note that each of Groups I - III is classified in class 514, subclass 2, meaning that a search of one Group would overlap significantly with a search of the other groups. Therefore, it is Applicant’s position that the restriction requirement is in error and that the Examiner has not shown that a serious burden would be required to examine all the claims.

In addition, the Examiner alleges that Invention I contains eight patentably distinct species as follows:

- “a) SEQ ID NO: 9
- b) SEQ ID NO: 10
- c) SEQ ID NO: 11
- d) SEQ ID NO: 12

- e) SEQ ID NO: 13
- f) SEQ ID NO: 14
- g) SEQ ID NO: 15
- h) SEQ ID NO: 16"

According to the Examiner, "These are different proteins from different species with different structures. They are thus patentably distinct. If Invention I is elected, applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which all claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-5 are generic. The examiner requests that applicant identify the consensus sequence of claim 11 or 12 appropriate to the elected species."


Applicants note that the election of species is for search purposes only and that, should the generic claim be deemed patentable, Applicants are entitled to a search and examination of a reasonable number of species. Should there be any questions after review of this paper, the Examiner is invited to contact the undersigned at (617) 832-1770.

In addition to this response, Applicants submit a request for a one month extension of time and the appropriate fee.

If there are any other fees due in connection with the filing of this Restriction Requirement, please charge the fees to our **Deposit Account No. 06-1448**.

Respectfully submitted,  
FOLEY, HOAG, & ELIOT

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